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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,459	09/30/2003	Shuqi Chen	IQA-004.02	2458

25181 7590 11/02/2005

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EXAMINER	
SIEFKE, SAMUEL P	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/605,459	CHEN, SHUQI	
	Examiner	Art Unit	
	Samuel P. Siefke	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10,12-19 and 22-36* is/are pending in the application.

4a) Of the above claim(s) *35,36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-10,12-19 and 22-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 2-10, 12-19, and 22-31 are pending. New claims 32-36 were added.

The Office Action mailed May 26, 2005 was a Non-Final Action and has been noted in the file.

Election/Restrictions

Newly submitted claims 35 and 36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 35 and 36 are directed towards a method of analyzing a fluid sample. Since the method can be practiced by hand, i.e. pouring a fluid sample into a column by hand, the methods can be properly restricted.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 35 and 36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Regarding claims 20 and 21, the Applicant requests the claims be rejoined and Examined because the claims depend from an allowable device claim and thereby qualify to be examined in the present application. There are no allowed claims in this

application or any related cases directed toward device claims. Claims 20 and 21 remain in a withdrawn status and will not be examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 33 and 34 claim 30 and 100 membranes stacked in a column. This is new matter because it was not described in the specification. The drawings, specifically fig. 2 shows 27 membranes stacked one on top another.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **2-10, 12-19, 22-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nieuwkerk et al. (USPN 5,438,128) in view of Imai et al. (USPN 5,057,438).

Nieuwkerk teaches a multi-layered testing column that comprises a plurality (1 to 20 layers) of microporous (pore size 0.1 to 12 microns) vertically stacked in a column (col. 3, lines 21-66), an inlet and outlet for flowing a sample liquid there through, the membrane layers are sized to occupy substantially all of the cross-section of the chamber (fig. 1a and 1b). Nieuwkerk teaches that the membranes are selected from the following microporous membrane materials such as cellulose, polyvinylidene fluoride, nylon (col. 5, lines 28-35). In the specification of the current application in paragraph 23, the applicant discloses that the membrane layers are preferably transparent to light, then goes on to disclose suitable materials for the membrane layers including cellulose, polyvinylidene fluoride and nylon. Because the prior art discloses the exact material as the current application, it is would appear that the prior art has the same properties of the instant membrane, i.e. transparent properties.

Nieuwkerk does not teach the membrane layers carrying a different anti-analyte on the surface.

Imai teaches a device for determining a plurality of species of antibodies or antigens in a sample that comprises flowing a sample through a stack of membranes that carry different antigens on each membrane (abstract). It would have been obvious to one having an ordinary skill in the art to modify Nieuwkerk to use antigens on a membrane instead of ions in order to test for cancerous growth in a sample (blood). It is also known in the art to use immunoassay for detection of species in a sample by binding an antigen to a carrier and passing a sample that has an antibody over or through a carrier and observing a detection based upon the binding of antigen antibody.

Regarding newly submitted claims 32-34, it would have been obvious to one having ordinary skill in the art to modify Nieuwkerk to employ a testing column with ten to one hundred membrane layers because it would allow a user to test for a plurality of analytes in a sample at one time. It is noted that Nieuwkerk teaches 20 membranes stacked one on top of another.

Response to Arguments

Applicant's arguments filed 7/26/05 have been fully considered but they are not persuasive. The Applicant argues, "There is no motivation to combine Nieuwkerk and Imai.....Nieuwkerk patent expressly teaches that its device is designed to test for one analyte at a time. See col. 8, lines 15-20." In response to applicant's argument that

there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, The applicant relies on one specific embodiment to discredit the prior art when Nieuwkerk specifically states that this is one of many embodiments that can be practiced with the device of Nieuwkerk. The teaching of Nieuwkerk is used to show a column with multiple membranes stacked one on top another. Imai provides the deficiencies of Nieuwkerk which when combined with Nieuwkerk discloses each and every limitation of the instant application. Further proper motivation was provided to combine the two teachings.

Regarding the arguments about the prior art not teaching membranes that are transparent to light, it is the Examiner's position that the prior art discloses the exact material as the current application. It would appear that the prior art has the same properties of the instant membrane, i.e. transparent properties. The applicant relies on cited prior art to show that not all materials relied on for the membranes are transparent. The prior art cited 4,42,298, is cellulose acetate which is different than cellulose. Therefore this reference is moot. USPN 6,562,178, 5,551,464 all have compounds added to the materials to create an opaque property. In Nieuwkerk, the membrane is thin enough that it will allow a selected wavelength of light through the membrane,

therefore it has substantially transparent properties. Example, with a strong enough lamp, materials relied upon will have some degree of transparent properties which allow a selected wavelength to pass.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke

October 28, 2005

Jill Warden
Supervisory Patent Examiner
Technology Center 1700